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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,785	07/24/2003	Michael Lebner	0156-2006US01	1187

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/626,785

Applicant(s)

LEBNER, MICHAEL

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/27/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/06 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/26/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 19-25 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0204740 to Weiser in view of US 5,979,450 to Baker et al. (claim 19) Weiser discloses a method for closing a laceration, the method comprising:
 - providing a two-component device comprising:
 - a first component **1a** having a first adhesive-backed anchoring member **2** [0037], and a first connecting members **5**; the first adhesive-backed anchoring member being protected by a two-stage release liner comprising:
 - a release liner **14a** with a bottom surface covering the adhesive-backed surface of the first anchoring member; and
 - a fold tab of liner **14a** (see Fig. 2; the portion that extends beyond fold line **20**) which is capable of being flipped back in order to expose a first a wound edge of the first anchoring member ([0045], [0047]);
 - a second component **1b** having the same structure as recited in the first component;
 - means for attaching the first connecting members to the second anchoring member and means for attaching the second connecting members to the first anchoring member (adhesives), wherein the first and second connecting members form bridging portions that span the wound edge (Figs. 5 and 6);

-attaching the first and second components to the skin on opposite sides of a wound (Fig. 5); and

-closing the laceration by adjusting the position of the first and second anchoring members by attaching the first and second connecting members to the second and first anchoring members, respectively (Fig. 6).

Weiser is silent with regards to the first and second components comprising a semi-rigid tab attached to the top surface of the release liner. However, Baker also discloses a similar polymer wound dressing with adhesive for application to skin adjacent an incision [column 1, lines 26-30 and lines 44-46], wherein the wound dressing has a "relatively stiff" handle (22) *protruding from the edge* of "flexible" film (16) [column 8, lines 45-49]. This arrangement provides a more rigid handle portion for removing the release liner

Therefore, it would have been obvious to one having ordinary skill in the art to modify the fold tab liner of Weiser to a semi-rigid, as taught by Baker, because it would allow the practitioner to better grasp the pull tab by providing a relatively stiff handle. It should be noted that the modified tab of Weiser/Baker is fully capable of being flipped back onto a portion of the liner while the liner to which the tab is not attached remains fully adhered to the anchoring member since only a portion of the release liner **14** would be modified to include a semi-rigid element.

(claim 20) A portion of the bridging link **5** is viewed as a pulling element.

(claims 21, 23-25, 29, 30 and 32) Weiser discloses the release liners having color coding to enable user distinction. Weiser is silent with regards to the pulling

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elements and the anchoring members. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Weiser to have the coding in the pulling elements and the anchoring members because Weiser already discloses the general idea of providing coding to provide the user distinction and that rearranging the parts that provide the coding would only require routine skill in the art. Modifying to include geometric distinction, or printed indicia instead of color coding would also only require routine skill in the art since these means for providing user distinction are obvious variants of each other.

(claim 22) The pulling elements are capable of being removed following application of the device.

(claim 27) The means for attaching the connecting members is an adhesive.

(claim 28) The first and second components each comprise a plurality of release liners, one on the anchoring member and the others in the connecting members.

(claim 31) See crease **20**.

6. Claims 26, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiser in view of Baker et al. and in further view of US 6,329,564 to Lebner.

The above combination of Weiser and Baker is silent with regards to the device being formed from a vapor-permeable material; and wherein the device is reinforced. However, Lebner discloses a similar type of wound closure device, wherein the device comprises anchoring members (5 and 25) and a pulling members (15 and 35); wherein the device is reinforced (col. 2, line 60 – col. 3, line 4), which provides the anchor with an edge that can be viewed as a wound edge bar. Therefore, it would have been

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obvious to one of ordinary skill in the art at the time invention the invention was made to modify the device of Weiser to include a vapor-permeable material because it allow the wound to "breathe". It would also be obvious to add a reinforcement to device of Weiser because to would prevent the anchoring member or the connecting members from being distorted from their original shape.

Response to Arguments

7. Applicant's arguments with respect to claims 19-34 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection are based on a reference provided in the IDS filed on 11/26/06.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Darwin P. Erez
Examiner
Art Unit 3731

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